

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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**Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee;
Notice of Meeting**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 28, 2001, from 8 a.m. to 5 p.m.

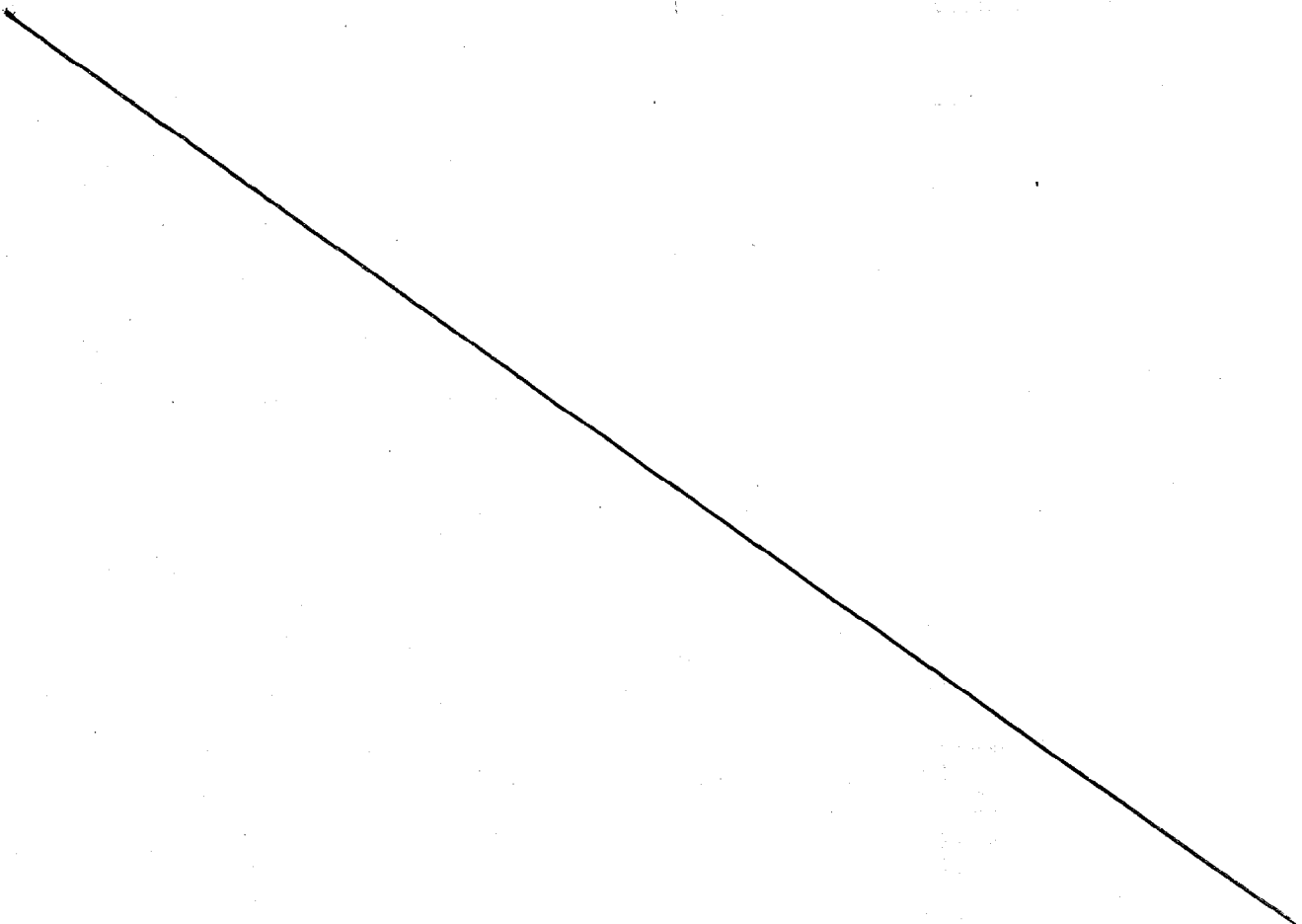
Location: Holiday Inn, Ballrooms A and B, Two Montgomery Village Ave., Gaithersburg, MD.

Contact: Kimberly Littleton Topper or Karen M. Templeton-Somers, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7001, or by e-mail at TopperK@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12542. Please call the Information Line for up-to-date information on this meeting.

Agenda: The subcommittee will discuss the implementation of the pediatric rule with regard to study designs, ethical and developmental considerations, and extrapolation of findings from adult to pediatric cancer patients.

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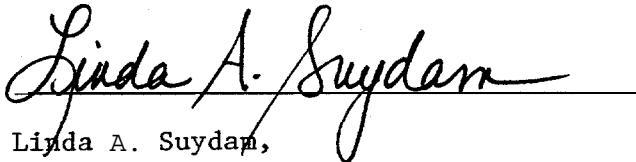
Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by November 16, 2001. Oral presentations from the public will be scheduled between approximately 8:15 a.m. and 8:45 a.m., and 1 p.m. and 1:30 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before November 16, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app.

2).

Dated: 10/12/01
October 12, 2001.



Linda A. Suydam,
Senior Associate Commissioner.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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